REMARKS

Claim 9 is canceled without prejudice to its continued prosecution in a continuation and/or divisional application.

The amendments to claims 1, 6-8, and 15 are fully supported by the description in the specification (e.g., page 7, line 17 to page 8, line 7; page 9, line 31 to page 10, line 13; etc.).

No new matter has been added. Upon entry of this Response, claims 1, 3, 6-8, 10-16, and 19-25 are present in the application with claims 7-8, 12, and 20-22 presently withdrawn as being drawn to non-elected specie.

Claim Rejections – 35 U.S.C.§ 112

1. The rejection of claim 9 under 35 U.S.C. § 112, second paragraph as being incomplete for omitting essential elements has been rendered moot by the cancellation without prejudice of this claim. Accordingly, withdrawal of this ground of rejection is respectfully requested.

2. The rejection of claims 1, 3, 6, 10-11, 13-16, 19, and 23-25 under 35 U.S.C. § 112, second paragraph as being incomplete for omitting essential elements is respectfully traversed.

Applicants respectfully traverse the assertion in the Office Action that a specific automated hematology analyzer with specific settings is required for the practice of the claimed invention (i.e., page 4 of Office Action). Indeed, the specification makes no statement that the elements in question are critical features. By way of example, the specification states only that "[a]utomated hematology analyzers, such as the multiparameter analyzers XE2100 and SE-9000...are presently preferred for use in accordance with the present invention (page 5, lines 10-13; emphasis added), and that the settings themselves "are optimized for the detection of megakaryocytes" (page 5, lines 13-16; emphasis added). Moreover, the specification clearly states that "[i]t should be emphasized that the settings themselves may vary with the type and/or condition of

PAGE 8/14 * RCVD AT 1/21/2008 1:20:49 PM [Eastern Standard Time] * SVR:USPTO-EFXRF-5/38 * DNIS:2738300 * CSID:13123214299 * DURATION (mm-ss):02-18

instrument used and that the numerical values shown in Table 1 are provided as guidelines" (page 9, lines 12-15). Notwithstanding, in view of the clear guidance and representative settings provided in the specification, one of ordinary skill in the art would be readily able to adapt the teachings of the specification to instruments other than those indicated as being presently preferable.

In light of the above, Applicants respectfully draw attention to MPEP 2164.08(c), which states as follows:

> Limiting an applicant to the preferred materials in the absence of limiting prior art would not serve the constitutional purpose of promoting the progress in the useful arts. Therefore, an enablement rejection based on the grounds that a disclosed critical limitation is missing from a claim should be made only when the language of the specification makes it clear that the limitation is critical for the invention to function as intended. Broad language in the disclosure, including the abstract, omitting an allegedly critical feature, tends to rebut the argument of criticality.

In view of the above, and in further view of the specification which clearly establishes that the recitations identified in the Office Action as being essential are merely preferred, Applicants respectfully submit that the claimed invention does not omit any essential elements. Accordingly, withdrawal of this ground of rejection is respectfully requested.

Claim Rejections – 35 U.S.C. § 103

1. The rejection of claim 9 under 35 U.S.C. § 103(a) as being unpatentable over *Sakata* (*Sysmex Journal International*, **2000**, *10*, No. 1, 41-46) in view of *Houwen et al.* (U.S. Patent No. 5,830,701), *Walters et al.* (*Laboratory Hematology*, **2000**, *6*, 83-92), and *Ota et al.* (*Haematologia*, **2000**, *30*, No. 1, 11-21) has been rendered moot by the cancellation without prejudice of this claim. Accordingly, withdrawal of this ground of rejection is respectfully requested.

2. The rejection of claims 1, 3, 6, 10-11, 13-16, 19, and 23-25 under 35 U.S.C. § 103(a) as being unpatentable over *Sakata* in view of *Houwen et al.*, *Walters et al.*, and *Ota et al.*, and the rejection of claims 11, 13, and 14 under 35 U.S.C. § 103(a) as being

PAGE 9/14 * RCVD AT 1/21/2008 1:20:49 PM [Eastern Standard Time] * SVR:USPTO-EFXRF-5/38 * DNIS:2738300 * CSID:13123214299 * DURATION (mm-ss):02-18

unpatentable over *Sakata* in view of *Houwen et al.*, *Walters et al.*, *Ota et al.*, and *Tomer et al.* (*Blood*, **1988**, *71*, No. 5, 1244-1252) are respectfully traversed.

None of *Sakata*, *Houwen et al.*, *Walters et al.*, *Ota et al.* or *Tomer et al.* teaches or suggests "generating a scattergram from the plurality of optical information using settings adjusted to display a megakaryocyte population" and "detecting the megakaryocyte if a population exists in a predetermined megakaryocyte region of the scattergram," as required by independent claim 1. Similarly, none of *Sakata*, *Houwen et al.*, *Walters et al.*, *Ota et al.* or *Tomer et al.* teaches or suggests " generating a scattergram by plotting the plurality of information using settings adjusted to display a megakaryocyte population," and "detecting the megakaryocyte if a population exists in a predetermined megakaryocyte region of the scattergram," as required by independent claim 15. Furthermore, none of *Sakata*, *Houwen et al.*, *Walters et al.*, *Ota et al.* or *Tomer et al.* teaches or suggests "generating a scattergram by plotting the scattered light and the fluorescent light using settings adjusted to display a megakaryocyte population," and "detecting the megakaryocyte if a population exists in a predetermined megakaryocyte region of the scattergram," as required by independent claim 23.

With regard to the arguments set forth in the Office Action (pages 7-11) justifying the various combinations of *Sakata*, *Houwen et al.*, *Walters et al.*, *Ota et al.*, and *Tomer et al.* in efforts to arrived at the claimed invention, Applicants respectfully submit that the proposed combinations are improper inasmuch as the applied references describe significantly different methods that clearly teach away from each other.

By way of example, *Sakata* describes a method for measuring nucleated red blood cells that involves staining cells with a fluorescent polymethine dye (e.g., page 41, column 1, last two paragraphs) while *Ota et al.* describes a fluorescent violet polymethine dye as a stain for megakaryocytes (e.g., page 11, abstract). However, in direct contrast to *Sakata* and *Ota et al.*, *Houwen et al.* describes a method of detecting hematopoietic progenitor cells that involves mixing a blood sample with a non-fluorescent reagent (e.g., a water-soluble surfactant, a solubilizing agent, an amino acid, a buffer agent or an osmolarity modifier; e.g., col. 4, line 59 to col. 6, line 31).

In addition to the contradictory teachings vis-à-vis the fluorescent or non-fluorescent nature of the reagent to be employed, the applied references also teach

PAGE 10/14 * RCVD AT 1/21/2008 1:20:49 PM [Eastern Standard Time] * SVR:USPTO-EFXRF-5/38 * DNIS:2738300 * CSID:13123214299 * DURATION (mm-ss):02-18

away from each other with respect to whether immunological or non-immunological methods should be used. For example, while *Sakata* and *Houwen et al.* describe methods that do not rely upon immunological principles, *Tomer et al.* describes a flow cytometric analysis in which megakaryocytes are labeled by immunological methods—specifically, using fluoresceinated IgG_1 mouse monoclonal antibodies (or $F(ab')_2$ fragments thereof) directed to a platelet-specific GPIIb/IIIa epitope (e.g., page 1245, column 1, second full paragraph; etc.).

In light of the above, Applicants respectfully draw attention to MPEP 2143.01(V), which states as follows:

> If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)

In addition, Applicants respectfully draw attention to MPEP 2143.01(VI), which states as follows:

> If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959)

For at least the reasons set forth above, Applicants respectfully submit that the claimed invention is neither anticipated by nor would have been obvious in view of *Sakata*, *Houwen et al.*, *Walters et al.*, *Ota et al.*, and *Tomer et al.*, individually or in combination. Accordingly, withdrawal of this ground of rejection is respectfully requested.

Conclusion

In view of the Amendment and Remarks set forth above, Applicants respectfully submit that the claimed invention is in condition for allowance. Early notification to such effect is earnestly solicited.

If for any reason the Examiner feels that the above Amendment and Remarks do not put the claims in condition to be allowed, and that a discussion would be helpful to

PAGE 11/14 * RCVD AT 1/21/2008 1:20:49 PM [Eastern Standard Time] * SVR:USPTO-EFXRF-5/38 * DNIS:2738300 * CSID:13123214299 * DURATION (mm-ss):02-18

advance prosecution, it is respectfully requested that the Examiner contact the undersigned agent directly at (312)-321-4257.

Respectfully submitted,

Gregory H. Zayia
Registration No. 48,059
Agent for Applicants

BRINKS HOFER GILSON & LIONE
P.O. BOX 10395
CHICAGO, ILLINOIS 60610
(312) 321-4200

PAGE 12/14 * RCVD AT 1/21/2008 1:20:49 PM [Eastern Standard Time] * SVR:USPTO-EFXRF-5/38 * DNIS:2738300 * CSID:13123214299 * DURATION (mm-ss):02-18